



THE INTERNATIONAL ASSOCIATION OF
LIONS CLUBS
(Lions Clubs International)

Naples Lions Club

Don Kennedy President

7648 Oleander Gate Dr. # 201

Naples, FL 34109

Naples Lions Club, Serving the Naples Community Since 1938

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01/04/2000

To: The Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 21 CFR Parts 210, 216, 820 and 1271 (Docket No. 97N-4845)

We, the undersigned members of the Naples, FL Lions Club do hereby urge your agency to reconsider the FDA Proposed Rule relative to Suitability Determination for donors of Human Cellular and Tissue Based Products.

During 1998, the Florida Lions Eye Bank obtained at the Dade, and Broward county Medical Examiners Office approximately 900 surgical quality corneas under Florida Statute 732.99185 (a law which has been in effect in this state since July 1977.) These corneas were then processed, screened, and provided for transplant surgery totally free of charge. Your proposed additional screening would require, in our opinion, an unnecessary and time consuming step in the process of obtaining corneas and would greatly hamper our efforts to serve Florida citizens who need eye surgery. If the proposed additional screening could insure that corneal tissue did not come from a donor having a communicable disease, we would agree that the additional step was necessary. However, the medical advisors we consult with do not believe that the proposed required screening which involves locating the donor's next of kin to ask certain questions would result in the additional safety of the corneas.

The Florida Lions Eye Bank has operated effectively since the passage of Florida Statute 732.99185, mostly due to cooperation of South Florida Medical Examiners. Proof of this is the fact that between July 1977 and July 1999 our eye bank provided over 28000 totally free corneas to people needing eye surgery. Most of these were obtained under the Florida Statute. During that time there has never been any evidence of transmission of Creutzfeldt Jakob Disease (CJD) to a recipient by any of those corneas. We agree with the opinion of Doctor Joseph H. Davis, Director Retired of Miami-Dade County Medical Examiner Department that the "ME donor pool has better quality control standards than the hospitalized chronically ill elderly pool." Until there is a proven blood test to detect CJD, the FDA cannot insure that any donor does not harbor that disease simply by requiring a donor medical history interview.

Contact Person: Lion Don Kennedy, Pres. 941-592-1195, irastampa@gulfcoast.net

CC: U.S. Senators and Representatives

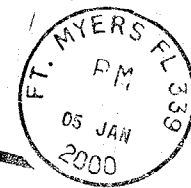
Signature sheet attached

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Name	Date
Lion Gertrude Crambaugh	1/4/2000
Lion E. L. Strade, P.D.B.	1/4/2000
Lion John Paul Wewereaux	1/4/2000
Lion George E. Martin	1/4/2000
Lion Roy McIntosh	1/4/2000
Lion Wayne E. Jerome	1/4/2000
Howard J. King	1/4/2000
Edward Markunas	1-4-2000
Don. Di Sano	1/4/00
Malcolm M. Miller	1/4/2000
Lion Lloyd Ranch	1/4/2000
Lion Joel Pearlman	1/4/00
Ralph Sheppard	1/4/00
George E. King	1-4-00
George E. King	1-4-00
O. King	1-4-00
Colores Bergtast 352. Gov.	1.4.00
Lion Edwin M. Kennedy	01.04.00
Lion Don Kennedy President	01.04.00

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